No. 90-476

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IN THE
SUPREME COURT OF THE UNITED STATES

OCTOBER TERM, 1990

WYETH-AYERST LABORATORIES DIVISION
OF AMERICAN HOME PRODUCTS CORPORATION,

Petitioner,

v.

MICHELLE GRAHAM, an Infant under the age of 18 who sues by her Parents, Guardians and Next Friends, CHARLES GRAHAM AND TAMMY GRAHAM,

Respondent.

PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE TENTH CIRCUIT

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QUESTIONS PRESENTED

1. Where federal law requires the manufacturer of a licensed prescription biological product, "DTP," sold in interstate commerce, to include labels and printed warning inserts, where the format and content of such labeling and inserts is subject to the control of the United States Food and Drug Administration ("FDA"), where such labeling and inserts have been specifically reviewed and approved by the FDA, where changes thereto require prior FDA approval, and where there has been no showing that the manufacturer has withheld any relevant information from the FDA, is a state tort claim based on the alleged "inadequacy" of the labeling and/or inserts pre-empted under the Supremacy Clause of the United States Constitution?

2. Where the design of the pertussis vaccine component of DTP sold in interstate commerce is pervasively regulated and licensed by the United States Food and Drug Administration ("FDA"), where the FDA has concluded that defendant's "whole cell" pertussis vaccine is safe and effective and has licensed DTP which contains said vaccine, where the FDA has found that certain "alternative" types of pertussis vaccine have not been shown to be adequately safe and effective for licensure in the United States, and where there has been no showing that the defendant has withheld any relevant information from the FDA, is a state tort law claim based on the alleged superiority of such alternative or other hypothetical vaccines and the alleged defectiveness of a whole cell pertussis vaccine pre-empted under the Supremacy Clause of the United States Constitution?

RULE 29.1 STATEMENT

Wyeth-Ayerst Laboratories (formerly Wyeth Laboratories) Division of American Home Products Corporation is an unincorporated division of American Home Products Corporation, a publicly-traded corporation. American Home Products Corporation has no parent corporation and has no subsidiaries or affiliates except for wholly-owned subsidiaries.

TABLE OF CONTENTS

	Page
QUESTIONS PRESENTED	i
RULE 29.1 STATEMENT	ii
TABLE OF AUTHORITIES	v
OPINIONS BELOW	1
JURISDICTION	2
CONSTITUTIONAL AND STATUTORY PROVISIONS INVOLVED	2
STATEMENT OF THE CASE	3
1. Respondent's Claims	3
2. Pertussis	4
3. Pertussis Vaccine And National Health Policy	4
4. Licensing And Regulation Of Pertussis Vaccine	8
5. Proceedings Below	13
REASONS FOR GRANTING THE WRIT	15
I. THE COURT SHOULD GRANT CERTIORARI BECAUSE THE JUDGMENT BELOW CONFLICTS WITH THE OPINION OF THE COURT OF APPEALS IN *HURLEY v. LEDERLE LABORATORIES*, 863 F.2D 1173 (5TH CIR. 1988)	15
II. THE COURT SHOULD GRANT CERTIORARI BECAUSE APPLICATION OF THE PRE-EMPTION DOCTRINE IS ESSENTIAL TO AVOID HAVING STATE LAW FRUSTRATE THE ACCOMPLISHMENT AND EXECUTION OF THE FULL PURPOSES AND OBJECTIVES OF CONGRESS WITH RESPECT TO OPTIMUM VACCINE DESIGN AND LABELING	

TABLE OF CONTENTS – *(Continued)*

Page

AND IMMUNIZATION POLICIES, MATTERS OF VITAL IMPORTANCE TO THE NATION'S PUBLIC HEALTH WHICH CONGRESS HAS COMMITTED TO THE DISCRETION AND CONTROL OF FEDERAL AGENCIES 19

CONCLUSION 30

TABLE OF AUTHORITIES

Cases: Page

Abbot v. American Cyanamid Company, 844 F.2d 1108 (4th Cir.), *cert. denied,* 488 U.S. 908 (1988) 15

Brown v. Hotel & Restaurant Employees Union, 468 U.S. 491 (1984) 20

Brown v. Superior Court, 44 Cal.3d 1049, 245 Cal. Rptr. 412, 751 P.2d 470 (1988) 28

Chicago & North Western Transportation Co. v. Kalo Brick & Tile Co., 450 U.S. 311 (1981). 20, 21

City of New York v. Federal Communications Commission, 486 U.S. 57 (1988) 20

Clark v. Secretary of Health and Human Services, 19 Cl. Ct. 113 (1989) 27

Cosmetic, Toiletry & Fragrance Ass'n v. Minnesota, 440 F. Supp. 1216 (D. Minn.), *aff'd,* 575 F.2d 1256 (8th Cir. 1978) 26

English v. General Electric Co., 110 S. Ct. 2270 (1990) 19

Farmers Union v. WDAY, 360 U.S. 525 (1959) 22

Felder v. Casey, 487 U.S. 131 (1988) 22

Feldman v. Lederle Laboratories, 234 N.J. Super. 559, 561 A.2d 288 (1989) 17

Fidelity Federal Sav. & Loan Ass'n v. de la Cuesta, 458 U.S. 141 (1982) 20

Florida Lime & Avocado Growers, Inc. v. Paul, 373 U.S. 132 (1963) 19

Gibbons v. Ogden, 22 U.S. (9 Wheat) 1 (1824) 19

Graham v. Wyeth Laboratories, 666 F. Supp. 1483 (D. Kan. 1987), *rev'd. and remanded,* 906 F.2d 1399 (10th Cir. 1990) ..... *passim*

TABLE OF AUTHORITIES – *(Continued)*

Cases:	Page
Hillsborough County v. Automated Medical Laboratories, Inc., 471 U.S. 707 (1985)	24
Hines v. Davidowitz, 312 U.S. 52 (1941)	19
Hurley v. Lederle Laboratories, 863 F.2d 1173 (5th Cir. 1988)	*passim*
International Paper Co. v. Ouellette, 479 U.S. 481 (1987)	21
Jacobson v. Massachusetts, 197 U.S. 11 (1905)	25
McDermott v. Wisconsin, 228 U.S. 115 (1913).	20, 26, 27
Offshore Logistics, Inc. v. Tallentire, 477 U.S. 207 (1986)	20
Perez v. Campbell, 402 U.S. 637 (1971)	20
San Diego Building Trades Council v. Garmon, 359 U.S. 236 (1959)	21
Silkwood v. Kerr-McGee Corp., 464 U.S. 238 (1984)	27
Taylor v. General Motors, 875 F.2d 816 (11th Cir. 1989), *cert. denied*, 110 S. Ct. 1781 (1990).	20-21, 29
Texas & Pacific Railway Co. v. Abilene Cotton Oil Co., 204 U.S. 426 (1907)	20
Toner v. Lederle Laboratories, 828 F.2d 510 (9th Cir. 1987), *cert. denied*, 485 U.S. 942 (1988)	23

UNITED STATES CONSTITUTION

Art. I, §8, cl. 3	2
Art. VI, cl. 2	2

TABLE OF AUTHORITIES – *(Continued)*

Page

STATUTES

Communicable Disease Control Amendments Act of 1972, Pub. L. No. 92-449, 86 Stat. 748 (1972) 6

Federal Food and Drugs Act of 1906, 34 Stat. 768 (1906) 9

Federal Food, Drug and Cosmetic Act, 21 U.S.C. §§301 et seq. (1982) 2, 9, 23, 29

National Traffic and Motor Vehicle Safety Act of 1966, 15 U.S.C. §§1381-1431 (1982)..... 29

National Childhood Vaccine Injury Compensation Act, 42 U.S.C. §§300aa-10 et seq. (West Supp. 1990)..... 16, 26-30

National Vaccine Program, 42 U.S.C. §§300aa-1 et seq. (West Supp. 1990) 2, 7, 27

Public Health Service Act of 1944, 42 U.S.C. §§201-300 (1982)..... 2, 9, 10, 23, 29

Vaccination Assistance Act of 1962, Pub. L. No. 87-868, 76 Stat. 1155 (1962)..... 5

Virus-Serum-Toxin Act of 1902, Pub. L. No. 57-244, 32 Stat. 728 (1902) 8-9

28 U.S.C. §1254(1) (1982)..... 2

K.S.A. 72-5209 (1988) 6

REGULATIONS

21 C.F.R. Part 600 (1979) 2, 10, 11

21 C.F.R. Part 601 (1979)..... 2, 10-13

21 C.F.R. Part 610 (1979)..... 2, 11-13

21 C.F.R. Part 620 (1979)..... 2, 12-13

TABLE OF AUTHORITIES – *(Continued)*

Page

LEGISLATIVE MATERIALS

H.R. Rep. No. 1835, 87th Cong., 2d Sess. (1962) 6

Intensive Immunization Programs: Hearings on H. R. 10541 Before the House Comm. on Interstate and Foreign Commerce, 87th Cong., 2d Sess. 44 (1962) 5

Preliminary Report of Progress in the Review of the Vaccination Picture in the Nation *reprinted in* 108 Cong. Rec. 11,745 (1962) 5

S. Rep. No. 1907, 87th Cong., 2nd Sess., *reprinted in* 1962 U.S. Code Cong. & Adm. News 3970.. 6

S. Rep. No. 825, 92nd Cong., 2nd Sess., *reprinted in* 1972 U.S. Code Cong. & Adm. News 3430.. 6

S. Rep. No. 1196, 95th Cong., 2d Sess. 6, 37 (1978) 6

H.R. Rep. No. 1063. 98th Cong., 2d Sess. (1984) 7

H.R. Rep. No. 905, 99th Cong., 2nd Sess., *reprinted in* 1986 U.S. Code Cong. & Adm. News 6287.. 28

H.R. Rep. No. 908, 99th Cong., 2d Sess. (1986) .. 26

OTHER AUTHORITIES

A Question of Competence: The Judicial Role in the Regulation of Pharmaceuticals, 103 Harv. L. Rev. 773 (1990) 25

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PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE TENTH CIRCUIT

Petitioner Wyeth-Ayerst Laboratories (formerly Wyeth Laboratories) Division of American Home Products Corporation respectfully prays that a writ of certiorari issue to review the judgment of the United States Court of Appeals for the Tenth Circuit which was entered in this case on June 25, 1990.

OPINIONS BELOW

The Opinion of the court of appeals below is reported at 906 F.2d 1399 (10th Cir. 1990), and is reprinted as Appendix A to this Petition (1a-42a). The

Opinion of the district court is reported at 666 F. Supp. 1483 (D. Kan. 1987), and is reprinted as Appendix B to this Petition (43a-77a).

JURISDICTION

The judgment of the United States Court of Appeals for the Tenth Circuit was entered on June 25, 1990. This Court has jurisdiction under 28 U.S.C. §1254(1) to review that judgment by writ of certiorari.

CONSTITUTIONAL AND STATUTORY PROVISIONS INVOLVED

This case involves Article I, Section 8, Clause 3, of the United States Constitution which provides that Congress shall have the power "to regulate Commerce . . . among the several states" and Article VI, Clause 2, of the Constitution, which provides that:

> This Constitution, and the Laws of the United States which shall be made in Pursuance thereof . . . shall be the supreme Law of the Land; and the Judges in every State shall be bound thereby, any Thing in the Constitution or Laws of any State to the Contrary notwithstanding.

This case also involves the Federal Food, Drug and Cosmetic Act, 21 U.S.C. §§301 *et seq.*, and the Public Health Service Act, 42 U.S.C. §§201 *et seq.*, specifically 42 U.S.C. §262 (Licensing and Regulation of Biological Products), and 42 U.S.C. §§300aa-1 *et seq.* (National Vaccine Program), and regulations promulgated thereunder, 21 C.F.R. Parts 600, 601, 610 and 620 (1979). The relevant parts of these statutes and regulations are submitted herewith as Appendix F (119a-238a).

STATEMENT OF THE CASE

1. Respondent's Claims

Respondent filed suit in the United States District Court for the District of Kansas on April 22, 1985. Federal jurisdiction is based on diversity, respondent being a citizen of Kansas and American Home Products Corporation being a Delaware corporation with its principal place of business in New York.

Respondent alleges that she was injured by her injection on March 17, 1980, with a licensed prescription biological product known as "DTP" which was produced and sold by petitioner. DTP contains a combination of diphtheria toxoid, tetanus toxoid and pertussis vaccine, and is used to protect infants and children against the serious and sometimes fatal diseases of diphtheria, tetanus ("lockjaw") and pertussis ("whooping cough").

Respondent contends that the pertussis vaccine component of DTP is defectively designed and that the package insert and other "labeling" material inadequately warn of the dangers of the pertussis vaccine.[1] The vaccine is defective, according to respondent, because it is a "whole cell" vaccine, *i.e.,* it includes the whole, killed, *B. pertussis* bacteria. Petitioner, respondent argues, should have switched from the whole cell vaccine to an allegedly "superior and safer" acellular, soluble, or other hypothetical alternative, but failed to do so, giving respondent "no choice other than the whole cell vaccine."[2] Respondent also argues that petitioner's

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1. Respondent did not contend below, and presented no evidence, that petitioner's DTP (and/or pertussis vaccine) was other than what it was intended to be, or that it was otherwise improperly "manufactured," as opposed to improperly "designed." Petitioner is not contending that state tort remedies based on improper manufacturing, or on the withholding of material information from the FDA, are pre-empted.

2. Brief of Appellee, 10th Cir., No. 88-1337, at p. 9.

package insert and labeling are inadequate in that they allegedly fail to specify a "cause and effect relationship between DTP and known reactions," fail to identify and quantify the presence of endotoxin and exotoxin in the vaccine, and understate the likelihood of severe adverse reactions.[3]

2. Pertussis

Pertussis is a serious and sometimes deadly respiratory disease.[4] It is caused by the *Bordetella pertussis* bacterium, an extremely complex organism.[5] The disease begins with mild coughing, progresses to severe coughing fits followed by an inspiratory whoop, and can result in brain damage or death.[6] The disease is highly contagious and, in the 1930's before widespread use of the whole cell pertussis vaccine, there were approximately 260,000 cases and thousands of deaths per year in the United States alone.[7]

3. Pertussis Vaccine And National Health Policy

Petitioner began producing DTP containing the whole cell pertussis vaccine in 1947.[8] By the end of the 1940's, the whole cell vaccine was in widespread use both in the United States and throughout much of the world.[9] By 1967, the United States' whooping cough

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3. *Id.* at 38.

4. Trial Transcript (hereafter "Tr.") 758-59, 4014, 5117-19; Defendant's Trial Exhibit (hereafter "DX") 65, pp. 346-47; DX 94, pp. 406-407; DX 243, p. 51041.

5. Tr. 242, 248, 2751, 2767-70, 4014, 4028-29, 4854-55; Plaintiff's Trial Exhibit (hereafter "PX") 59B, p. 7; DX 65, p. 198; DX 243, p. 51041.

6. Tr. 4014-15, 4454; DX 65, pp. 198, 346-47; DX 243, p. 51041.

7. DX 44, p. 8; DX 65, pp. 198, 347; DX 94, pp. 406-07; DX 243, p. 51041.

8. Tr. 300.

9. DX 65, pp. 198-99; DX 94, p. 405.

mortality rate had decreased to 1/250th of the 1930 rate.[10] Only an average of 1,835 cases and ten deaths occurred per year from 1975 to 1985 in the United States.[11] Pertussis, however, remains a killer of large numbers of children in countries where immunization is not widespread. Countries which have experienced reduced immunization rates have quickly suffered epidemic outbreaks.[12]

Immunization of children with the whole cell pertussis vaccine is a "vital part of our nation's public health policy."[13] Since at least 1962 and the passage of the Vaccination Assistance Act,[14] the federal government has taken the lead in promoting nationwide immunization. The 1962 Act, proposed and passed in light of what were considered "excellent vaccines,"[15] reflected a federal initiative "to stamp out four serious diseases — poliomyelitis, diphtheria, whooping cough (pertussis) and tetanus."[16] Congress went beyond merely authoriz-

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10. DX 243, p. 51041.

11. DX 94, p. 406.

12. Brief for the United States as *Amicus Curiae* submitted to the Tenth Circuit on behalf of the Food and Drug Administration ("FDA"), the Centers for Disease Control ("CDC") and the National Institutes of Health ("NIH"), App. D at 91a. The United States' *amicus* brief sets out in detail the role of the federal government in regulating, promoting, and developing vaccines and its views on the proven value of the whole cell vaccine. It is therefore reprinted in full as Appendix D to this Petition and is cited hereafter as "U.S. *Amicus* Br., App. D." The brief "expresses no opinion on the question of whether federal law preempts plaintiff's state tort remedies in this case" App. D at 84a.

13. U.S. *Amicus* Br., App. D at 87a.

14. Pub. L. No. 87-868, 76 Stat. 1155 (1962).

15. *See, e.g.*, Preliminary Report of Progress in the Review of the Vaccination Picture in the Nation, *reprinted* in 108 Cong. Rec. 11,745 (1962).

16. *Intensive Immunization Programs: Hearings on H.R. 10541 Before the House Comm. on Interstate and Foreign Commerce*, 87th Cong., 2d Sess. 44 (1962) (statement of Abraham Ribicoff, Secretary of Health, Education and Welfare). Most states,

ing the marketing of these vaccines; it launched an aggressive program actively to encourage their use. Both the House Report and the Senate Report expressed concerns about incomplete immunization and embraced the objective of maximizing nationwide coverage.[17]

Subsequent congressional enactments reflect a continuing strong commitment to immunization. The Senate Committee Report on the Communicable Disease Control Amendments Act of 1972[18] noted Congress' "unmistakable affirmation . . . that the Federal Government has a continuing responsibility" and a "leadership role" in the prevention of contagious diseases.[19] In 1978, a Senate Committee Report, noting the disparity between the 60% national immunization rate and the federal goal of 90% immunization, approved new funding levels that "should allow HEW to make certain that 90% of American children are immunized against polio, rubella, measles, pertussis, diphtheria, typhoid and mumps."[20] In 1982, a House Committee Report, approving further funding, noted with pride the success of Congress' "Childhood Immunization Initiative," the purpose of which was "to raise immunization levels against polio, measles, rubella, diphtheria, tetanus, mumps and pertussis and to establish a permanent

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including Kansas, now require immunization against these diseases prior to entering school. *See* K.S.A. 72-5209.

17. The Senate Report described the need for a "two-stage national effort," including "intensive" vaccination campaigns aimed at all unvaccinated, susceptible persons, followed-up with a strengthening of ongoing vaccination programs. S. Rep. No. 1907, 87th Cong., 2d Sess., *reprinted in* 1962 U.S. Code Cong. & Adm. News 3970, 3978. The House Report echoed the desire to "administer the vaccine to substantially all of the population in the United States," in order to avoid the "totally unnecessary risk" of epidemics. H.R. Rep. No. 1835, 87th Cong., 2d Sess. 3 (1962).

18. Pub. L. No. 92-449, 86 Stat. 748 (1972).

19. S. Rep. No. 825, 92d Cong., 2d Sess., *reprinted* in 1972 U.S. Code Cong. & Adm. News 3430, 3433, 3434, 3436.

20. S. Rep. No. 1196, 95th Cong., 2d Sess. 6, 37 (1978).

system to provide comprehensive immunization services to more than three million children born in the United States each year."[21] Most recently, Congress directed the establishment of a comprehensive National Vaccine Program "to achieve optimal prevention of human infectious diseases through immunization and to achieve optimal prevention against adverse reactions to vaccines." 42 U.S.C. §300aa-l.

The central role and interest of federal public health authorities in promoting the use of the whole cell pertussis vaccine is set forth in the U.S. *Amicus* Brief submitted below:

> Federal public health authorities, including the Food and Drug Administration (FDA), the Centers for Disease Control (CDC), the National Institutes of Health (NIH), and other agencies, have, for almost forty years, promoted vaccination of the populace with diphtheria-tetanus-pertussis (DTP) vaccines containing as one of their three components the so-called 'whole cell' pertussis vaccine. . . . These agencies are unaware of any other pertussis vaccine produced in the world today that has been adequately demonstrated to be both safer than and as effective as the 'whole cell' vaccine licensed for sale by the FDA.

U.S. *Amicus* Br., App. D at 84a-85a.

> HHS supports the continuing manufacture and marketing of the 'whole cell' vaccine because no alternative formulation has been adequately proven to be both safer than and as effective as the 'whole cell' vaccine. HHS's support for continued production of this product is consistent with the vigorous

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21. H.R. Rep. No. 1063, 98th Cong., 2d Sess. 2 (1984).

> recommendations of all sectors of the medical community, both public and private, which have carefully analyzed the dangers of the disease and the benefits and risks associated with the vaccine.
>
> Experts still have not determined what part of the whole *B. pertussis* cell used in the 'whole cell' vaccine provides immunity to the recipient. HHS, the governments of other nations, and numerous private firms are actively seeking an improved vaccine that provides the protection of the 'whole cell' design. Until the time that HHS is convinced that such an alternative vaccine has been found, it will continue to advocate the use of 'whole cell' vaccine as a vital part of our nation's public health policy.

U.S. *Amicus* Br., App. D at 86a-87a.

> In sum, based on their evaluation of the available scientific and medical evidence, HHS's public health experts have concluded that alternative pertussis vaccines *have not yet been adequately shown to be safe and effective for licensure in the United States,* although studies are continuing.

U.S. *Amicus* Br., App. D at 98a (emphasis added).

4. Licensing And Regulation Of Pertussis Vaccine

In addition to promoting the use of the whole cell vaccine, federal authorities also control – through licensing, regulatory standards, and the testing and "release" of DTP for sale on a lot-by-lot basis – its formulation and production. The power to determine which *designs* of biological products shall be permitted to pass in interstate commerce and to determine the content of labeling and other information has resided with the federal government for almost 90 years. In enacting the Virus-Serum-Toxin Act of 1902, Congress first assumed federal control – through licensing – of the interstate

sale of biologicals.[22] The 1902 Act was consolidated into the Public Health Service Act of 1944, 42 U.S.C. §§201-300 ("PHSA"). Biologicals, because they also fall within the definition of "drugs" in the Federal Food, Drug and Cosmetic Act (*see* 21 U.S.C. §321(g)(1)), have also been continually regulated pursuant to that Act as well as its predecessor, the Federal Food and Drugs Act of 1906.[23] These statutes are intended "to insure the continued safety, purity, and potency" of biological products such as DTP (42 U.S.C. §262(d)) and to protect the public against any false or misleading labeling or misbranded products (21 U.S.C. §§352, 392(b); 42 U.S.C. §262(g)).[24]

Under the PHSA and the regulations promulgated thereunder, a manufacturer of biological products, *i.e.*, products made from living organisms, must secure both an "establishment" and "product" license. 42 U.S.C.

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22. Pub. L. No. 57-244, 32 Stat. 728 (1902).

23. 34 Stat. 768 (1906).

24. At the time relevant to this case, the regulatory power provided under the above statutes was vested in the FDA's Bureau of Biologics. 21 C.F.R. §600.3(d) (1979). The Bureau of Biologics is now known as the Center for Biologics Evaluation and Research ("CBER"). 21 C.F.R. §600.3(d) (1990). The doctors and scientists working at the Pertussis Branch of the CBER, at the NIH, and at the CDC are and have been international leaders in this scientific field. For decades they have published papers on a wide variety of topics, which range from information about the basic properties of the *B. pertussis* bacterial organism to the design, content and preparation of potential new pertussis vaccines which may be on the horizon; they have conducted collaborative studies among domestic manufacturers and participated in collaborative studies among the regulatory laboratories of foreign nations; they have hosted or attended all of the International Symposia on Pertussis, and will host the Sixth International Symposium on Pertussis at the end of September, 1990 (its program is attached as Appendix G, 238a-251a); and they have participated in the international standardization of pertussis vaccine and the tests to be used thereon, both as among nations and as part of World Health Organization programs. *See* U.S. *Amicus* Br., App. D. at 98a-102a.

§262; 21 C.F.R. §601.1.[25] Pursuant to this licensing authority, the FDA exercises stringent control over what products are produced and how they are produced. An *establishment* license may issue "only after inspection of the establishment and upon a determination that the establishment complies with applicable standards prescribed in the regulations . . . ." 21 C.F.R. §601.10. The standards prescribe, among other things, the qualifications and duties of personnel involved in the manufacture of the biological products; the physical requirements for the establishments, including lighting and ventilation requirements; apparatus, supplies and equipment requirements; restrictions on building and equipment use; and care, quarantine, immunization, bleeding and reporting requirements for animals used in the manufacture of products at the establishment. 21 C.F.R. §§600.10-11. The regulations also include mandatory requirements for the maintenance and retention of records, and for the retention of samples of each Lot of each product manufactured at the establishment sufficient for safety and potency testing. 21 C.F.R. §§600.12-14.

In order to obtain and to maintain a current *product* license for any biological product, a manufacturer must demonstrate that the product meets all prescribed standards of safety, purity and potency. 21 C.F.R. §§601.2(a), 601.20. The manufacturer is required to provide the FDA with, for example, a full description of the manufacturing method, data establishing stability of the product, samples of the product, summaries of results of tests performed on Lots represented by the samples, and specimens of the "labeling (including the package insert)," enclosures and containers proposed to be used with the product. *Id.* No product license may

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25. Drugs which are not biologic in nature are not required to be licensed and the degree of federal control is thus substantially less. *See* 21 U.S.C. §§301 *et seq.*

remain in effect unless the FDA determines that the product continues to comply with the standards prescribed in the regulations, 21 C.F.R. §601.20; that the establishment manufacturing the product complies with the establishment standards prescribed in the regulations, 21 C.F.R. §601.20(a); and that no part of the process relating to the manufacture of the product would, in the FDA's judgment, impair assurances of continued safety, purity and potency as provided by the regulations. 21 C.F.R. §§601.20(b).[26]

Section 610 of the regulations sets forth certain standards applicable to all biological products which have been licensed. In general, the regulations provide

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26. Petitioner's "product license" permits only the production and sale of a whole cell vaccine. *See* 906 F.2d at 1403, App. A at 6a-7a. The FDA did, in the early 1960's, license Eli Lilly & Company to incorporate a non-whole cell pertussis vaccine into its DTP. That product was never subjected to "controlled clinical efficacy trials . . . comparable to those performed on 'whole cell' vaccine in the 1940's and 1950's" and Eli Lilly voluntarily ceased marketing the product in the late 1970's. U.S. *Amicus* Br., App. D at 92a. In 1982, petitioner, having acquired Eli Lilly's "know-how," made and clinically tested a non-whole cell "Lilly-like" vaccine. Petitioner then submitted a license amendment application to allow it to market DTP containing such a vaccine. The FDA, however, based on comparative clinical efficacy and safety data for the whole cell and non-whole cell vaccines, declined to grant the request. U.S. *Amicus* Br., App. D at 92a-94a. Tr. 659, 3098-99. *See* 906 F.2d at 1403, App. A at 6a-7a. The state of the art then turned to a new acellular pertussis vaccine patented by the Japanese NIH, variations of which were made by several Japanese companies. Wyeth obtained the vaccine from one company and refined and incorporated it into a DTP product which was clinically tested both by Wyeth (Tr. 4050) and by the National Institutes of Allergy and Infectious Disease (Tr. 4052). Later, an aceliular pertussis vaccine was tested in Sweden (Tr. 4054) under the joint sponsorship of, *inter alia* , the Centers for Disease Control (*See* Tr. 4063) and the World Health Organization, but the results were disappointing, U.S. *Amicus* Br., App. D at 94a-97a. To date no such vaccine has been licensed in the United States. The whole cell product remains the standard for the entire world, except Japan. *Id.*

that no Lot of any licensed product may be released prior to the completion of tests for conformity with standards applicable to each product. 21 C.F.R. §610. Each applicable test must be made on each Lot. *Id.* Specific tests and procedures which must be performed on all biological products are set forth in the regulations. 21 C.F.R. §§610.10-14. These include tests for potency, general safety, sterility, purity and identity. *Id.* The regulations also set out standards for constituent materials used in the product and other matters. 21 C.F.R. §§610.15, 610.50-65.

Samples of each Lot, together with protocols showing the results of each test, must be available for inspection by the Director of the Office of Biologics Research and Review. 21 C.F.R. §610.2(a). A manufacturer may not distribute in interstate commerce any Lot of a product until the Lot is actually released for sale by the FDA. *Id.*

In addition to the foregoing establishment licensing, product licensing, and general biological products standards, the regulations also set out standards specifically applicable to the manufacture and sale of the pertussis vaccine. Section 620.1 prescribes permissible constituent ingredients of the pertussis vaccine and specifies that the vaccine "shall be an aqueous preparation of either killed whole *Bordetella pertussis* bacteria or a fraction of *Bordetella pertussis* bacteria." Section 620.2 sets out regulations relating to the growth, content, and method of detoxification of the bacteria used in the vaccine, and to the use of preservatives in the vaccine. 21 C.F.R. §§620.2-3. Specific requirements relating to mandatory potency and toxicity tests are also set forth. 21 C.F.R. §§620.4-5. Finally, the regulations require that each Lot be tested for safety by specified procedures, and that a sample of each Lot, along with protocols, which summarize the manufacturing process

and the results of all toxicity and potency tests for each Lot, be submitted to the FDA for review. 21 C.F.R. §620.6.[27]

The FDA also regulates the labeling, including the package insert, of licensed prescription vaccines and other biologicals. 21 C.F.R. §§601.3, 610.60-61. The content of such materials cannot be changed without prior FDA approval. 21 C.F.R. §601.12(b).

5. Proceedings Below

Petitioner moved prior to trial for summary judgment on the grcund, *inter alia,* that respondent's design and warning claims were pre-empted by federal law. Alternatively, petitioner argued that it was entitled, on the undisputed facts, to judgment under Kansas law. The trial court rejected Wyeth's pre-emption argument in its entirety, reasoning that the jury could assign the FDA's judgment on proper vaccine design and labeling "the weight it deserves." *Graham v. Wyeth Laboratories,* 666 F. Supp. at 1491, App. B at 57a.

The case was tried to a jury beginning in August, 1987. Petitioner established at trial that its DTP containing a whole cell vaccine had been licensed, tested, approved and released for sale by the FDA and that its package insert was the one approved, and thus required, by the FDA. It alsc showed that in 1982 it had applied for a license amendment to allow use of a non-whole cell pertussis vaccine and that the FDA has not granted that application. No evidence was presented that petitioner had deviated in any way from the FDA requirements as to either the design of the pertussis vaccine or the information and warnings accompanying it. Nor was there any evidence that petitioner had ever misled the FDA or withheld from it any material information which

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27. Under these regulations every lot of petitioner's DTP was submitted to, tested by, and released for sale in interstate commerce by, the FDA. (*See* Tr. 502, 5518).

might have caused the FDA to act differently. Indeed, respondent stipulated that petitioner was in full conformity with all FDA requirements (Tr. 502), and the trial court held that there had been "no showing that [petitioner] has been out of compliance with any of the FDA requisites." (Tr. 5518).

Nevertheless, respondent was permitted to argue to the jury that petitioner should have been marketing an unlicensed acellular, or other hypothetical unlicensed, vaccine, instead of the FDA-licensed whole cell vaccine, and that the FDA-approved package insert and labeling were inadequate to reasonably inform a prescribing physician of the risks and benefits of the vaccine. The jury, given free rein to reject the FDA's judgment in these matters, did so. It declared the federally-approved and licensed whole cell vaccine to be "in a defective condition unreasonably dangerous to persons as a result of its design" as well as because of "inadequate warnings" and found petitioner negligent "in regard to its DTP whole cell vaccine" with respect to "testing, designing, and/or warning." It awarded the respondent $15 million.[28] Petitioner's motions for judgment notwithstanding the verdict, for a new trial based on the weight of the evidence and various errors in the conduct of the trial, and for a new trial based on newly-discovered evidence were denied and petitioner appealed.

In support of its appeal from the denial of its JNOV motion, petitioner again argued that respondent's claims were pre-empted. In affirming the denial of petitioner's JNOV motion, the Tenth Circuit held that the "district court [had] correctly analyzed the pre-emption issue" and stated that:

> [F]ederal pre-emption does not prevent state tort law awards arising from improperly manufactured drugs or vaccines, even in situations where the drugs or

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28. The jury's Answers to Special Interrogatories are reprinted as Appendix C to this Petition (78a-79a).

vaccines have met the FDA's minimum standards for licensing.

906 F.2d at 1404, n.9, App. A at 11a.

Finding numerous errors in the conduct of the trial and finding merit in petitioner's motion for a new trial based on newly-discovered evidence, however, the court below reversed the judgment in respondent's favor and remanded for a new trial. *Id.*

REASONS FOR GRANTING THE WRIT

I. THE COURT SHOULD GRANT CERTIORARI BECAUSE THE JUDGMENT BELOW CONFLICTS WITH THE OPINION OF THE COURT OF APPEALS IN *HURLEY v. LEDERLE LABORATORIES*, 863 F.2D 1173 (5TH CIR. 1988).

In its appeal to the Tenth Circuit, petitioner relied upon the Fifth Circuit's decision in *Hurley v. Lederle Laboratories*, 863 F.2d 1173 (5th Cir. 1988), App. E (105a-118a). The *Hurley* case presented the same sort of warning and design defect claims with respect to the whole cell pertussis vaccine as respondent has raised in the instant case. In holding that "federal pre-emption does not prevent state tort law awards" in DTP cases and rejecting in full petitioner's pre-emption argument, the Tenth Circuit cited *Hurley* with approval. 906 F.2d at 1004, n. 9, App. A at 11a. The decision below, however, squarely conflicts with the *Hurley* decision, which recognizes the need for a limited application of the pre-emption doctrine on the record developed in this case.[29]

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29. The only other court of appeals decision on the issue of pre-emption in a case involving DTP is *Abbot v. American Cyanamid Company*, 844 F.2d 1108 (4th Cir.), *cert. denied*, 488 U.S. 908 (1988), in which the court of appeals reversed the entry of summary judgment for the defendant-manufacturer on pre-emption grounds. The court in *Abbot* premised its conclusions almost entirely on Congress' adoption in 1986 of the National Vaccine Compensation

The *Hurley* court, while finding neither explicit Congressional pre-emption nor a preclusive occupancy of the field, squarely held that the sort of warning claim raised here is pre-empted on "conflict" pre-emption grounds and that a similar result should "likely" be reached with respect to the design defect claim. 863 F.2d at 1179, App. E at 117a.

> A state law determination on [the proper warning] should not be interjected to overrule the decisions of the FDA. Such a procedure would place vaccine manufacturers in a position where they could not comply with both obligations . . . . [A]ssuming that the FDA has processed all the relevant and available information in arriving at the prescribed warning its decision as to the proper wording must preempt by implication that of a state.

863 F.2d at 1179, App. E at 116a.

The Fifth Circuit reversed the entry of summary judgment in *Hurley* and remanded for trial solely to allow resolution of a very narrow fact issue:

> A factual issue remains . . . as to whether the manufacturer provided the FDA all the necessary and available information on which to base the warning. Thus, the only question that can be presented to the jury consistent with the federal regulatory scheme is whether the manufacturer withheld, either at the time the FDA decided the content of the warning, or since then, information that would have changed the FDA's decision.

863 F.2d at 1179-80, App. E at 116a-117a. The court directed that the narrow factual issue be presented to the jury by special interrogatory. It concluded that such

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NOTES *(Continued)*

Act, 42 U.S.C. §§300aa-10 *et seq.* For the reasons set forth *infra* at pp. 26-30 that reliance was misplaced.

an approach was dictated by both the public interest and fairness to manufacturers.

> This special procedure is justified by the federal interest in encouraging manufacturers to produce vaccines, in that those manufacturers need some assurance that if they follow certain prescribed procedures, such as including an FDA-approved warning, they are complying with the law.

863 F.2d at 1180, App. E at 117a. *Accord, Feldman v. Lederle Laboratories,* 234 N.J. Super. 559, 561 A.2d 288 (1989) (claim that warning accompanying antibiotic was inadequate was pre-empted by federal law where warning was FDA-approved and manufacturer could not alter it without FDA approval).

The court in *Hurley* also considered whether a "parallel analysis to that applied in the warning context should apply to design-defect claims."

> That is, although FDA regulation has not preempted the entire field of design defect, assuming that the FDA processed all necessary and available data, does FDA approval preempt a claim that the product in design is unreasonably dangerous?

863 F.2d at 1180, n.4, App. E at 117a. Although it declined to decide that issue without "the benefit of a district court's reasoning," the Fifth Circuit made it clear that its "holding against general preemption does not necessarily exclude the possibility of a specific preemption" and stated that it "would seem likely" that the same analysis applied to the warning claim should be applied to the design defect claim. *Id.*

The decision below, although purporting to rely on *Hurley,* cannot be reconciled with it. Neither the Tenth Circuit opinion nor the district court opinion which it adopted on the pre-emption issue recognizes any applicability of pre-emption principles to the instant case.

Unlike *Hurley,* where no factual record existed at the time of the Fifth Circuit's consideration of the pre-emption issue, the instant case was decided below on a fully-developed factual record. In the trial of this case, there was no showing that petitioner had withheld any information from the FDA that would have resulted in the FDA requiring a different warning or abandoning the whole cell vaccine. Whatever doubts could exist on that score should easily be put to rest by considering the views of the FDA, NIH and CDC set forth in the government's *amicus* brief in this case (App. D, 80a-103a). That submission shows that the nation's public health bodies still regard the whole cell vaccine as the superior product and still support "the continuing manufacture and marketing of the 'whole cell' vaccine because no alternative formulation has been adequately proven to be both safer than and as effective as the 'whole cell' vaccine." U.S. *Amicus* Br., App. D at 86a. Similarly, these agencies remain convinced that the FDA-approved package insert used by petitioner in 1980 is appropriate. U.S. *Amicus* Br., App. D at 99a-100a. These federal agencies are at the forefront of vaccine development and effective immunization policies and it has not been — and could not be — seriously argued that petitioner in 1980 withheld from them information that would have in any way altered their views as to proper warnings or optimum vaccine design.

Thus, if the decision in Hurley were to govern this case, petitioner would be entitled to a judgment notwithstanding the verdict. Certiorari should be granted to resolve the conflict between the circuits.[30]

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30. Under the terms of the Tenth Circuit's remand, the pre-emption defense is foreclosed to petitioner; issues which should be reserved to the FDA will therefore again be submitted to a jury. While petitioner may, of course, prevail on other grounds on the retrial, the issues presented here are of sufficient import, and the conflict in the courts is sufficiently direct, that the Court should resolve these issues now.

II. THE COURT SHOULD GRANT CERTIORARI BECAUSE APPLICATION OF THE PRE-EMPTION DOCTRINE IS ESSENTIAL TO AVOID HAVING STATE LAW FRUSTRATE THE ACCOMPLISHMENT AND EXECUTION OF THE FULL PURPOSES AND OBJECTIVES OF CONGRESS WITH RESPECT TO OPTIMUM VACCINE DESIGN AND LABELING AND IMMUNIZATION POLICIES, MATTERS OF VITAL IMPORTANCE TO THE NATION'S PUBLIC HEALTH WHICH CONGRESS HAS COMMITTED TO THE DISCRETION AND CONTROL OF FEDERAL AGENCIES.

Even where Congress has neither expressly pre-empted state law nor fully "occupied the field," the Court has long held that:

> [S]tate law is pre-empted to the extent that it actually conflicts with federal law.
>
> Thus, the Court has found pre-emption where it is impossible for a private party to comply with both state and federal requirements, *see, e.g., Florida Lime & Avocado Growers, Inc. v. Paul,* 373 U.S. 132, 142-143, 83 S. Ct. 1210, 1217-1218, 10 L.Ed.2d 248 (1963), or where state law 'stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.' *Hines v. Davidowitz,* 312 U.S. 52, 67, 61 S. Ct. 399, 404, 85 L.Ed. 581 (1941).

English v. General Electric Company, 110 S. Ct. 2270, 2275 (1990). State law which has "come into collision with an act of Congress" must yield to the "supreme Law of the Land." *Gibbons v. Ogden,* 22 U.S. (9 Wheat) 1, 210 (1824).

Where, as here, Congress has established federal administrative agencies and delegated to them the task of administering and implementing federal statutes, pre-emption will be found where state law conflicts with,

or frustrates the objectives of, statutorily-authorized agency actions. As the Court recently emphasized in *City of New York v. Federal Communications Commission*, 486 U.S. 57 (1988):

> [W]here state law is claimed to be pre-empted by federal regulation, a 'narrow focus on Congress' intent to supersede state law [is] misdirected' for '[a] pre-emptive regulation's force does not depend on express congressional authorization to displace state law.' *Fidelity Federal Sav. & Loan Ass'n v. De la Cuesta*, 458 U.S. 141, 154, 102 S. Ct. 3014, 3023, 73 L.Ed.2d 664 (1982).

486 U.S. at 64. Thus, it has been held that "the statutorily authorized regulations of an agency will pre-empt any state or local law that conflicts with such regulations or frustrates the purposes thereof." *Id.* Specifically, pre-emption of state law in conflict with federal food and drug regulation has long been recognized. *McDermott v. Wisconsin*, 228 U.S. 115 (1913).

Conflict preemption, as defined by the Court, does not depend upon the purpose of the respective federal and state laws, but rather upon the effect that a state law conflict would have upon supreme federal law. *Perez v. Campbell*, 402 U.S. 637, 651-52 (1971). Where there is an "actual conflict," state law is "preempted by direct operation of the Supremacy Clause." *Brown v. Hotel & Restaurant Employees & Bartenders International Union*, 468 U.S. 491, 501 (1984).

Indeed, this Court has long recognized that even express intent to preserve state remedies (so-called "saving clauses") will not preclude conflict pre-emption, because a federal act cannot be read to "destroy itself." *Texas & Pacific Railway Co. v. Abeline Cotton Oil Co.*, 204 U.S. 426, 446 (1907). *Accord, e.g., Offshore Logistics, Inc. v. Tallentire*, 477 U.S. 207, 210-11 (1986); *Chicago & Northwest Railway Co. v. Kalo Brick & Tile*

Co., 450 U.S. 311, 328-31 (1981); *Taylor v. General Motors Corp.*, 875 F.2d 816, 826 (11th Cir. 1989), *cert. denied*, 110 S.Ct. 1781 (1990).

Most recently in *International Paper Co. v. Ouellette*, 479 U.S. 481 (1987), the Court held that conflict pre-emption operated, despite an express saving clause, to bar a common-law tort suit that sought to prevent a discharger of liquid waste from exercising its federal permit. The Court held that allowing such state law actions would subject dischargers to "a variety of common-law rules established by different states," which would "undermine" "clear and identifiable" federal standards. *Id.* at 494-96.

> It would be extraordinary for Congress, after devising an elaborate permit system that sets clear standards, to tolerate common-law suits that have the potential to undermine this regulatory structure.

Id. at 497. The state and federal laws in *International Paper* both sought to promote clean water, but conflict pre-emption arose because "state law . . . interfere[d] with the methods by which the federal statute was designed to reach this goal." *Id.* at 494.

As the Court has often recognized, pre-emption analysis must focus "on the nature of the activities which the States have sought to regulate, rather than on the method of regulation adopted," and "regulation can be as effectively exerted through an award of damages as through some form of preventive relief." *San Diego Building Trades Council v. Garmon*, 359 U.S. 236, 243, 247 (1959). Because "the obligation to pay compensation can be, indeed is designed to be, a potent method of governing conduct and controlling policy," *Garmon*, 359 U.S. at 247, the Court has often refused to allow damages to be awarded under state law for conduct encouraged, or required, by federal law. *See, e.g., International Paper Co.*, (pre-emption of damage suits for water pollution); *Chicago & North Western*

Transportation Co., (pre-emption of damage suits for freight overcharges); *Farmers Union v. WDAY*, 360 U.S. 525 (1959) (pre-emption of damage suits for defamation). That has been true even in cases of strong state interest. As stated in *Farmers Union:*

> We are aware that causes of action for libel are widely recognized throughout the states. But we have not hesitated to abrogate state law where satisfied that its enforcement would stand 'as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.'

360 U.S. at 535 (citations omitted). *See Felder v. Casey*, 487 U.S. 131, 138 (1988) ("the relative importance to the state of its own law is not material when there is a conflict with a valid federal law").

Applying the foregoing principles to the instant case, it is clear that respondent's design defect and warning claims do "come into collision with" and do serve as an obstacle to, the full "purposes and objectives" of both Congress and the federal agencies charged with regulating vaccines and implementing the nation's public health policies.

The essence of respondent's case is that petitioner should not have manufactured and sold DTP containing the whole cell pertussis vaccine, but should have instead marketed DTP containing the supposedly "superior and safer" (but unlicensed) acellular vaccine or some other hypothetical unlicensed vaccine. Even assuming – as petitioner does solely for the purposes of argument – that respondent could produce qualified experts to support the contention that an acellular vaccine is somehow "better" than a whole cell vaccine, the fact remains that Congress has vested the responsibility and authority for determining optimum vaccine design with the federal government's expert scientists and physicians, not with lay jurors.

The conclusions of the FDA, NIH, and CDC are unequivocal. They are "unaware of any other pertussis

vaccine produced in the world today that has been adequately demonstrated to be both safer than and as effective as the 'whole cell' vaccine licensed for sale by the FDA." U.S. *Amicus* Br., App. D at 85a. Until these agencies – not a lay jury – are "convinced that [a superior] vaccine has been found, [they] will continue to advocate the use of 'whole cell' vaccine as a vital part of our nation's public health policy" (*Id.* at 87a) and will not issue licenses to petitioner or other manufacturers for unproven alternatives. *Id.* at 98a.

The FDA has licensed petitioner to market DTP *only* containing a whole cell pertussis vaccine. It has never licensed petitioner to market DTP containing anything other than the whole cell vaccine. Indeed, when petitioner requested a license amendment to allow incorporation of non-whole cell pertussis vaccine into its DTP, the FDA declined to allow the amendment.[31] Tr. 659, 3098-99; U.S. *Amicus* Br., App. D at 92a-94a. As the court below recognized, in the absence of a license allowing incorporation of a non-whole cell pertussis vaccine into its DTP, petitioner would have faced federal civil and criminal law penalties if it had marketed that product in interstate commerce. 42 U.S.C. §262(f); 21 U.S.C. §§331(d), 333(a), 355(a). 906 F.2d at 1403, App. A at 7a.

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31. The FDA's decision was based on the fact that in comparative clinical trials, there had been "two serious reactions in children receiving the [non-whole cell] vaccine" and the non-whole cell vaccine "had less potency than 'whole cell' vaccine." U.S. *Amicus* Br., App. D at 93a. *Compare Toner v. Lederle Laboratories,* 828 F.2d 510, 514 (9th Cir. 1987), *cert. denied,* 485 U.S. 942 (1988), affirming a negligence verdict against DTP manufacturers in "the absence of evidence that the FDA would not have approved [alternative vaccine] had [the manufacturer] submitted the product." In *Toner,* Justice Kennedy questioned "whether jury verdicts are the most sensible way of allocating risks and costs regarding vaccines that have been proved beneficial," but no pre-emption issue had been raised and the court was thus required to "defer to . . . state law." *Id.*

The licensure or non-licensure of a pertussis vaccine is plainly within the scope of the FDA's congressionally-delegated authority. Moreover, promotion of the whole cell vaccine as an essential part of national public health policies is plainly within the scope of authority vested by Congress in the CDC and NIH. Allowing lay jurors to second guess these judgments, to superimpose their non-scientific preferences, and to award damages on the basis of their belief that these agencies are wrong about the optimum design of the pertussis vaccine is unfair to petitioner, and prevents the accomplishment of legitimate and important federal purposes and objectives. The jury's verdict, declaring the whole cell vaccine "defective" and "unreasonably dangerous," is directly contrary to the FDA's decision that the product is safe and efficacious and properly licensed. The jurors' preference for alternative vaccines cannot be reconciled with the conclusions of federal experts who "have concluded that alternative pertussis vaccines have not yet been adequately shown to be safe and effective for licensure in the United States." U.S. *Amicus* Br., App. D at 98a.

If juries are permitted under state law to reject the FDA's conclusion regarding proper vaccine "design" and/or warning, national uniformity and expert regulation will be displaced by *ad hoc* guesswork and speculation, perhaps fueled more by sympathy or passion than by legitimate scientific analysis.[32] Kansas, through its

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32. The court below erred in describing the FDA's regulation of pertussis vaccine as merely establishing "minimum," rather than uniform, standards. 906 F.2d at 1404, n.9, App. A at 11a. *Compare Hillsborough County v. Automated Medical Laboratories, Inc.*, 471 U.S. 707 (1985), where the FDA promulgated certain plasmapheris regulations, but stated "[t]hese regulations are not intended to usurp the powers of State or local authorities to regulate plasmapheris procedures in their localities." 471 U.S. at 714, *quoting* 38 Fed. Reg. 19365 (1973). There, unlike here, there was an ample basis to find that "the federal interest at stake . . . is to insure

juries, might prescribe one standard, Mississippi another, New Jersey yet another and so forth, tailored to fit the circumstances of each local plaintiff. Different juries in different cases in any given state might even require different "designs" within a single state. Such varying, non-expert regulation of vaccine design would produce uninformed chaos, rather than the expert regulation and uniformity which Congress intended in vesting in the FDA the final say on which vaccine designs and which warnings best serve the public health needs of the country. As one commentator has recently noted:

> [A] design-defect liability judgment is, by definition, a determination that a given medication should not be marketed under its current design. This judicial determination does not merely supplement standards established by the FDA; it undermines the aggregate risk calculus properly undertaken by the FDA in its capacity as 'public health promoter [and] public health protector.'

Note, *A Question of Competence: The Judicial Role in the Regulation of Pharmaceuticals,* 103 Harv. L. Rev. 773, 788 (1990) (quoting 50 Fed. Reg. 7452 (1985)).[33]

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minimum standards, not uniform standards." 471 U.S. at 722, n.5.

33. This Court, in rejecting an attack on a state's compulsory smallpox vaccination law, long ago recognized the inappropriateness of having courts or juries second-guess duly adopted public health policies regarding immunization:

> We must assume that, when the statute in question was passed, the legislature of Massachusetts was not unaware of . . . opposing theories, and was compelled, of necessity, to choose between them. It was not compelled to commit a matter involving the public health and safety to the final decision of a court or jury. It is no part of the function of a court or jury to determine which one of two modes was likely to be the most effective for the protection of the public against disease.

Jacobson v. Massachusetts, 197 U.S. 11, 30-31 (1905).

A state regulation or statute which declared the whole cell vaccine to be defective and purported to require the use of an unlicensed alternative vaccine would, under long-standing authority, be pre-empted. *See McDermott v. Wisconsin,* 228 U.S. at 124-37; *Cosmetic, Toiletry & Fragrance Ass'n v. Minnesota,* 449 F. Supp. 1216 (D. Minn.), *aff'd,* 575 F.2d 1256 (8th Cir. 1978). The same result should apply where state law would accomplish through the jury-driven award of damages on the judicial side what it could not do through direct regulation by the legislative or administrative arms of state government. This is not a situation where the award of damages can be reconciled with the accomplishment of federal goals. The threat of multi-million dollar damage awards has the inevitable effect of drastically increasing prices and pushing suppliers of FDA-approved vaccines out of the market.[34]

The district court in the instant case premised its decision rejecting pre-emption largely on Congress' enactment of the National Vaccine Injury Compensation Act, 42 U.S.C. §§300aa-10-34. *Graham,* 666 F. Supp. at 1491-93, App. B at 58a-60a. That reliance was misplaced.

First, the actual conflict between state and federal law existed in 1980, at the time of the immunization, and legislation enacted six years later cannot alter that historical fact. Petitioner should not be made liable for doing what federal law required – or not doing what

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34. Petitioner, faced at the time with a rapidly growing number of DTP damage suits and the cost and unavailability of insurance, withdrew from the DTP market in 1984. *See* U.S. *Amicus* Br., App. D. at 86a, 101a, H.R. Rep. No. 908, 99th Cong., 2d Sess. (1986), Part 1 at 6-7. In response to the threat of shortages, petitioner thereafter, for several years, produced pertussis vaccine for sale to another licensed producer which then incorporated it into its DTP. Of the ten private manufacturers once licensed to produce DTP in the United States, only two remain. U.S. *Amicus* Br., App. D at 89a.

federal law prohibited – at the time it acted. *See, e.g., McDermott v. Wisconsin,* 228 U.S. at 124-37.

Second, the compensation provisions were enacted as part of the overall "National Vaccine Program" which recognized the overriding responsibility of the Department of Health and Human Services "to achieve optimal prevention of human infectious diseases through immunization and to achieve optimal prevention against adverse reactions to vaccines." 42 U.S.C. §300aa-1. Jury second-guessing of actions taken in furtherance of those goals cannot be reconciled with the intent of Congress.

Third, the Compensation Act eliminates an oft-cited reason for refusing to find pre-emption in personal injury cases – the usual absence of any federal remedy. *See, e.g., Silkwood v. Kerr-McGee Corp.,* 464 U.S. 238, 251 (1984). Under the Compensation Act, respondent may seek to avail herself of the Act's no-fault remedies. Such remedies, for immunizations occurring prior to the October 1, 1988 effective date of the Act, include compensation for full future medical care and other costs.[35]

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35. For persons such as respondent, the Compensation Act provides, *inter alia,* for an award sufficient to cover all projected lifetime expenses for:

> diagnosis, medical or other remedial care, rehabilitation, developmental evaluation, special education, vocational training and placement, case management services, counseling, emotional or behavioral therapy, residential and custodial care and service expenses, special equipment, related travel expenses, and facilities determined to be reasonably necessary.

42 U.S.C. §300aa-15(a)(1)(B)(iii). Claimants demonstrating injuries comparable to those alleged by respondent have received multi-million dollar awards under the Act. *See, e.g., Clark v. Secretary of Health and Human Services,* 19 Cl. Ct. 113 (1989).

The district court erroneously concluded that those receiving immunizations more than eight years prior to the effective date – such as respondent – are not eligible to receive benefits under the Compensation Act. 666 F. Supp. at 1492, App. B at 59a-60a. It is irrelevant that respondent was immunized more than eight years prior to the Act's effective date; she is still eligible to participate in

Fourth, in enacting the legislation, Congress did not purport to address whether particular *types* of state tort claims did or did not conflict with the accomplishment of federal objectives and policies. To the extent "traditional" state tort remedies were mentioned at all in the legislative history, it was only by way of explaining that such remedies were not "satisfactory." *See* H.R. Rep. No. 905, 99th Cong., 2d Sess., Part 1 at 6 (1986), *reprinted in* 1986 U.S. Code Cong. & Adm. News 6287, 6344, 6347.

Finally, the Act itself contains explicitly pre-emptive language governing suits arising out of immunizations occurring after the October 1, 1988 effective date of the Act:

> No vaccine manufacturer shall be liable in a civil action for damages arising from a vaccine-related injury or death associated with the administration of a vaccine after October 1, 1988, if the injury or death resulted from side effects that were unavoidable even though the vaccine was properly prepared and was accompanied by proper directions and warnings.

42 U.S.C. §300aa-22(b)(1). The precise application of this provision has not been decided and it is not at issue in this case, but it would seem to reflect *explicit* Congressional pre-emption of all design defect claims, leaving only disputes over proper "preparation," *i.e.*, disputes as to "manufacturing," rather than design, defects, an issue not present in this case. *See generally, Brown v. Superior Court,* 44 Cal.3d 1049, 245 Cal. Rptr. 412, 424, n.12, 751 P.2d 470, 482, n.12 (1988) (distinguishing

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NOTES *(Continued)*

the Program. 42 U.S.C. §300aa-11. Any person who was immunized prior to the effective date of the Act may file a claim under the Act within two years of such effective date, *i.e.*, prior to October 1, 1990. 42 U.S.C. §300aa-16(a)(1).

between manufacturing and design defects).[36]

The Act further contains a presumption that a vaccine is "accompanied by proper directions and warnings," as long as the manufacturer has "complied in all material respects with all requests under the Federal Food, Drug and Cosmetic Act and section 262" of the PHSA. §300aa-22(b)(2). A plaintiff may escape these presumptive limits only upon proof that the manufacturer has engaged in fraud or "intentional and wrongful withholding of information" regarding the vaccine – the same types of exceptions recognized in *Hurley* – or upon "clear and convincing evidence" of a lack of due care notwithstanding compliance with federal law. *Id.*, §§300aa-23(d)(2)(A), (B). While this "clear and convincing" exception could be read to limit somewhat the pre-emptive effect of the Act with respect to warning claims, it is more likely intended simply to reflect that compliance with federal laws and regulations does not provide an ironclad shield against liability irrespective of any mishandling, mispreparation or other negligence with regard to the product. As such, it is entirely congruent with the result reached in *Hurley* and the argument petitioner makes in this case. *See,*

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36. In other contexts, the courts of appeals have readily recognized that even where Congress has explicitly preserved common law liability remedies, certain types of design defect claims are pre-empted. In enacting the National Traffic and Motor Vehicle Safety Act of 1966, 15 U.S.C. §§1381-1431, for example, empowering federal promulgation of automobile safety standards, Congress precluded states from adopting varying state standards, but explicitly provided that compliance with any federal standard would "not exempt any person from any liability under common law." 15 U.S.C. §§1392(d), 1397(c). Nonetheless, common law personal injury actions alleging that automobiles without air bags are defectively designed have consistently been found to be pre-empted by virtue of the federal agency action allowing manufacturers the option of using air bags or seat belts. *See, e.g., Taylor v. General Motors,* 875 F.2d at 818-20.

Hurley, 863 F.2d at. 1178, stating that the Compensation Act "doomed" the argument that *all* claims involving vaccine injuries were pre-empted, but recognizing the viability of pre-emption with respect to the design defect and warning claims made in this case.

Thus, the adoption in 1986 of the National Vaccine Program, including the compensation provisions, cannot be read to legitimize the sort of claim made in this case. The pre-emption doctrine is properly invoked here to avoid an actual conflict between state and federal law and the frustration of vitally important federal objectives.

CONCLUSION

For the foregoing reasons, the Petition for a Writ of Certiorari should be granted.

Respectfully submitted,

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